IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 12 CASES LISTED IN EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MOTION AND MEMORANDUM TO EXCLUDE THE GENERAL CAUSATION EXPERT OPINIONS OF DR. KONSTANTIN WALMSLEY FOR WAVE 12

Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) move to exclude Dr. Walmsley's general causation opinions because they fail to satisfy the standard set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and as expressed by this Court in prior rulings. This motion applies to the Wave 12 cases identified in Exhibit A attached hereto.

Notice of Adoption

In previous Waves, through certain case-specific reports, Dr. Walmsley has provided general-causation opinions regarding the adequacy of Ethicon's IFUs and the availability of safer alternative procedures. Ethicon hereby adopts and incorporates by reference the *Daubert* motions filed against Dr. Walmsley on these issues for Ethicon Waves 1, 2, 3, and 4. Dkts. 1998 (Wave 1 motion), 1999 (Wave 1 memorandum in support); Dkts. 2451 (Wave 2 motion), 2454 (Wave 2 memorandum in support); Dkts. 2823 (Wave 3 motion), 2824 (Wave 3 memorandum in

support); Dkts. 3585 (Wave 4 motion), 3586 (Wave 4 memorandum).[1] For the reasons expressed in these motions, Ethicon respectfully requests that the Court exclude Dr. Walmsley's testimony on these issues, which are offered in similar form in certain case-specific reports in Wave 12.

Motion to Exclude Dr. Walmsley's New Wave 12 General-Causation Opinions

In addition to the general-causation opinions Dr. Walmsley has offered in certain case-specific reports in past Waves, in the following three Wave 12 cases, Dr. Walmsley seeks to offer new general-causation opinions, which this Court has not previously addressed, by incorporating them into his case-specific expert reports: Ex. B, Expert Report of Dr. Walmsley, *Kimberly Raney v. Ethicon Inc., et al.,* 2:13cv10010 (Walmsley Rpt (Raney)); Ex. C, Expert Report of Dr. Walmsley, *Cynthia Newman v. Ethicon Inc., et al.,* 2:14-cv-24066 (Walmsley Rpt (Newman)).

None of Dr. Walmsley's new opinions is supported by reliable methodology. Instead, within these case-specific reports, he only "summarizes" his general causation opinions: he never explains them, and he never provides *any* scientific analysis, literature citation, or other support for his conclusions. Although Dr. Walmsley suggests that these general-causation opinions have been supported and explained in "prior general liability reports" (*see, e.g.*, Ex. B, Walmsley Rpt at 3), he has never submitted a separate "general report" in this litigation—in any Wave, for any product. While he states generally that he relied on reports authored by Dr. Jerry Blaivas and Dr. Daniel Elliott, he does not specify which of their reports he relied on, does not cite to any portions of the reports, or even identify which opinions (if any) he relied on. Walmsley Rpt. (Raney) at 4; Walmsely Rpt. (Newman) at 4. Rather, he simply asserts bald conclusions, stating:

[1] *See also* Dkt. 2652 Wave 1 Memorandum Opinion and Order); Dkt. 3556 (Wave 2 Order Adopting Wave 1 Memorandum Opinion and Order); Dkt. 4215 (Wave 3 Order Adopting Wave 1Memorandum Opinion and Order); Dkt. 6280 (Wave 4 Order Adopting Wave 1Memorandum Opinion and Order).

- Ethicon's mesh is "not suitable for its intended application as permanent prosthetic implants" because it is cytotoxic, its "pores are too small, it is a heavy weight mesh, it degrades over time, and it can cause chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biolfilm formation and infections; in addition, the mesh has sharp edges, and has been found to rope, curl, and deform. Under tension, the pores have been found to collapse."
- Ethicon knew that its mesh devices were not appropriate for use, but it failed to modify/change the mesh.
- Ethicon failed to act as a reasonable and prudent medical device manufacturing.
- "Ethicon's mesh devices have design flaws because they cannot adequately describe, inform, or explain to physicians how to properly 'tension' the device."
- Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ("MSDS") for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina.
- The design of these devices are flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.
- Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents.
- Ethicon's warnings and disclosures of adverse events in their Instructions for Use ("IFU") for these devices have been inadequate.

- The benefits of these mesh products are outweighed by the severe, debilitating, and life changing complications associated with them and there were safer alternative options available.

See Ex., B Walmsley Rpt. (Raney) at 3-10. Incredibly, Dr. Walmsley offers absolutely no support or analysis for these opinions.[2]

It is well established that expert opinions must be "based on scientific knowledge that will assist the trier of fact in understanding or determining a fact in issue," and the proposed opinion must arise from a reliable methodology. *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995) (citation omitted) (explaining that the proffered opinion "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known" (citation omitted)). As the Fourth Circuit Court of Appeals recently reiterated, "[t]he touchstones for admissibility under *Daubert* are two: reliability and relevancy. . . . [C]ourts must look to the entire process that produced an opinion to determine whether the expert's work satisfies *Daubert*'s fundamental command: that expert testimony be reliable and relevant." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No. II)*, MDL 2502, 892 F.3d 624, 637–38 (4th Cir. 2018) (internal quotations and citations omitted).

This Court has routinely excluded opinions where an expert, as here, fails to provide sufficient scientific support for such generalized statements. "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014) (GOODWIN, J.), *as amended* (Oct. 29, 2014) (citing *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y.2005)). "[I]f the relevant scientific literature

[2] Although Dr. Walmsley generally references his reliance list at the beginning of his reports, he provides no explanation as to how the references on that list support his opinions and provides no citations within his report indicating which references support which opinions.

contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.* (citing, *inter alia*, *Rezulin*, 369 F. Supp. 2d at 425); *Mathison v. Boston Sci. Corp.*, 2015 WL 2124991, *7-8 (S.D.W. Va. 2015)(excluding opinions of Dr. Margolis regarding failure rates where he failed to explain why he disagreed with contrary studies and discounted scientific studies and instead gave patients "the benefit of the doubt" as to complication rates). Here, because Dr. Walmsley has failed to support his general causation opinions *at all*, much less consider or explain contrary studies, they should be excluded in their entirety.

Moreover, these opinions contain impermissible statements regarding the state-of-mind of Ethicon and the implanting physicians in these cases. *See, e.g.*, Walmsley Rpt. (Raney) at 7 ("Ethicon knew that its . . . mesh devices were not appropriate for use"); *id.* at 13 (opining that because the IFU was inadequate "Ms. Raney's implanting physician . . . did not know about many of these risks" and was not "fully able to consent her"). This Court has consistently found that experts in this MDL may not testify about device manufacturers' "knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 702-03 (S.D.W. Va. 2014). *See, e.g.*, *Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012) (excluding expert testimony based on defendant's corporate documents); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

Finally, in addition to Dr. Walmsley's opinions regarding the adequacy of the IFU being unreliable, he is also unqualified to offer these opinions. This Court has consistently held that

medical doctors, including urogynecologists and urologists, are not qualified to opine as to what risks or complications should or should not be included in the relevant IFU. *See, e.g., In re: Ethicon, Inc.*, MDL No. 2327, 2016 WL 4958312, at *3 (S.D. W. Va. Aug. 25, 2016) (citing *Wise v. C.R. Bard., Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015)).

Dr. Walmsley is unqualified to offer these opinions, and general-causation opinions lack reliability and relevance and should be excluded in their entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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